The Viveve System is a Non- Invasive Treatment for Vaginal Introital Laxity that Improve Sexual Function in Adult Female Subjects

viveve™

Women's sexual health. It matters.

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Disclosures

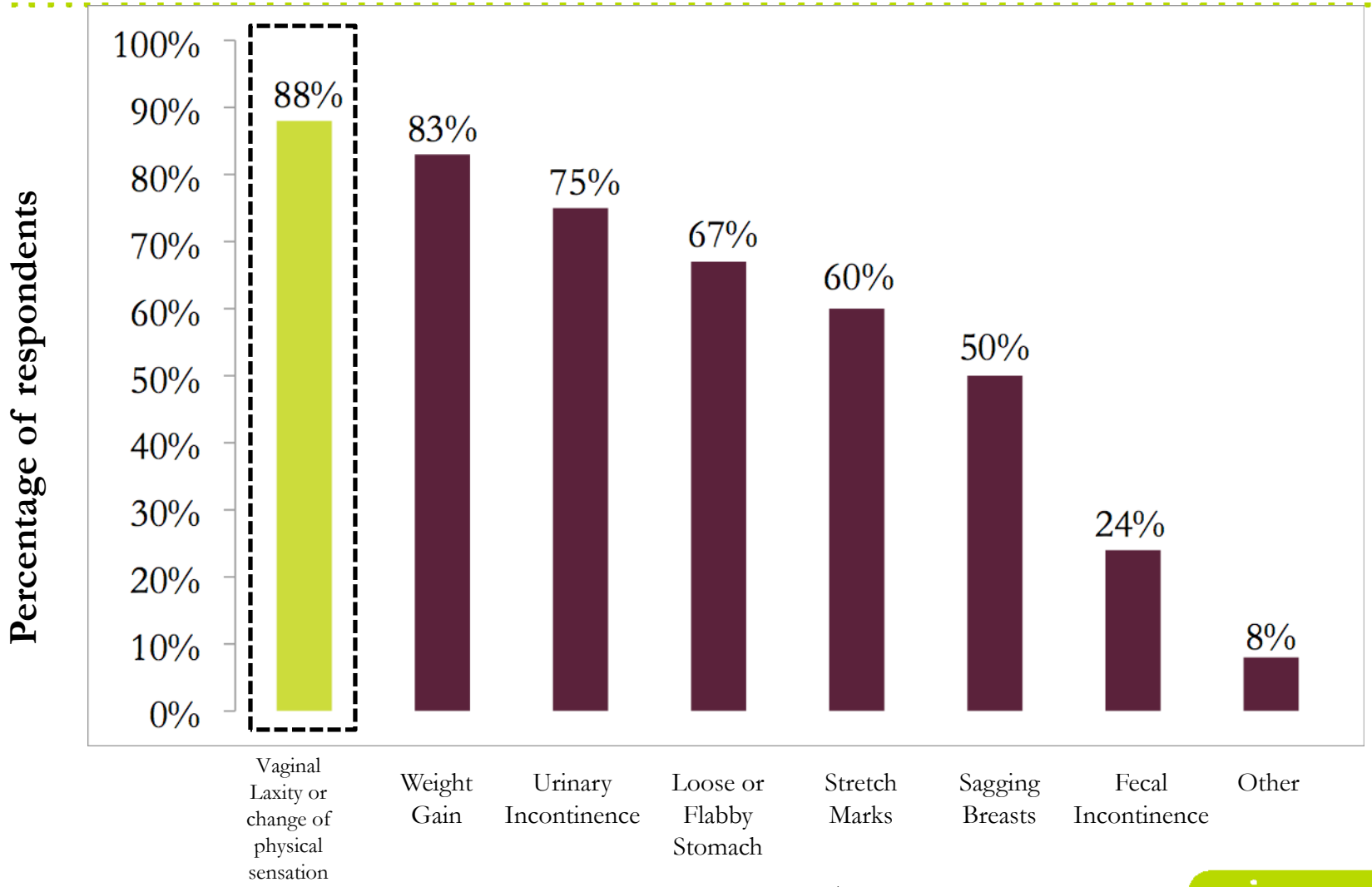
- *Dr. Michael L Krychman wishes to disclose the following: He is the Chief Medical Consultant for Viveve Medical, Inc, and chairs the Company's Medical Advisory Board.*

- *This research was funded by Viveve Medical Inc*

The Condition, The Problem, and Current Solutions

- Vaginal childbirth permanently stretches vaginal tissue
- Resulting looseness can cause:
  - diminished physical sensation during intercourse
  - reduction of sexual satisfaction
  - change in relationship with her sexual partner
- Infrequently discussed with OB/GYNs
  - physicians have no proven options to offer
- Solutions are lacking
  - Surgery and kegels

Patient Reported Physical Changes After Pregnancy (Physician Perspective)



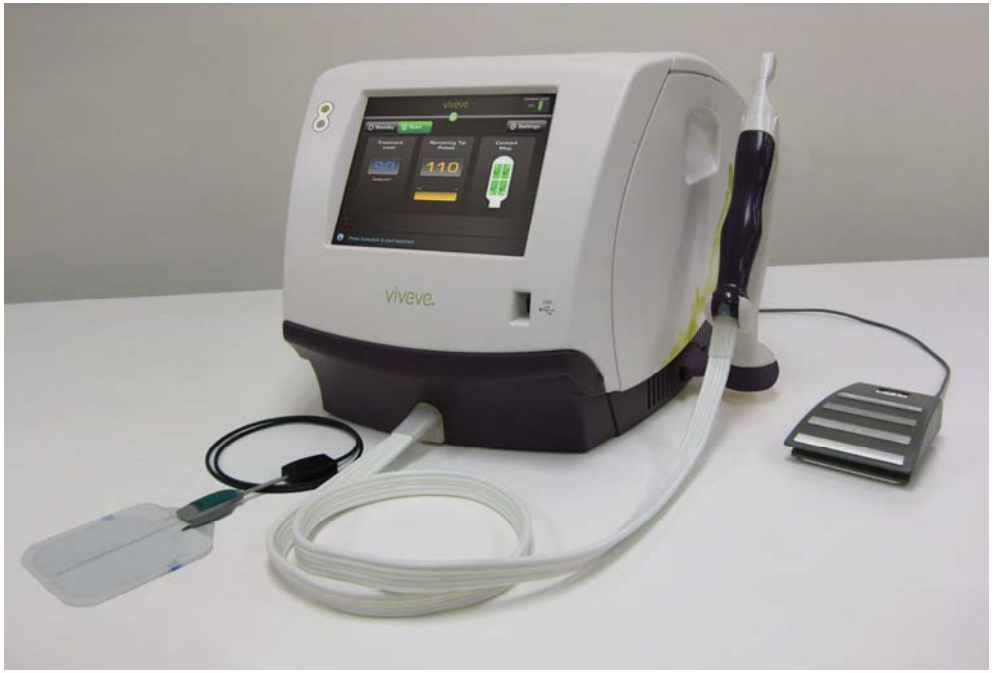
Viveve Quantitative Physician Research of 525 US Ob/Gyn physicians, conducted Oct 2009

Treatment Paradigm: Vaginal Laxity

- **Behavioral /Kegel Exercises**
  - Significant patient directed teaching
  - Time consuming, Poor efficacy and compliance
  - Addresses pelvic floor muscles, not introital tissue
- **Viveve Treatment**
  - Non-invasive 30 minute office based procedure
  - Quick and easy recovery
  - Proven safety and efficacy
  - Cost effective
- **Surgical Intervention**
  - Invasive, painful surgical operation
  - Significant recovery period
  - Potential for serious surgical complications
  - May require repeat operation
  - Very costly

The Viveve Non-Surgical Solution

- Patented, proven, reverse-thermal gradient technology
- Radiofrequency ("RF") generator with integrated cooling module
- Hand piece and disposable treatment tip



Treatment Protocol

Think of vaginal opening as face of a clock

- Place treatment tip at 1 o' clock position immediately behind vaginal opening
- Depress foot pedal to delivery 3 phased pulse (cooling/heating/cooling)
- Rotate treatment tip 1 cm clockwise and deliver 3 phased pulse
- Repeat until treatment tip is positioned at 11 o'clock position
- Avoid urethra (11 o' clock to 1 o' clock)
- Reposition treatment tip at 1 o'clock position and repeat process
- Treatment is complete after 5 full passes or ~100 pulses

Procedure Benefits

- Non-surgical
- In-office, 30 minute treatment, can be repeated
- Simple and safe with no anesthesia required
- No downtime

Past

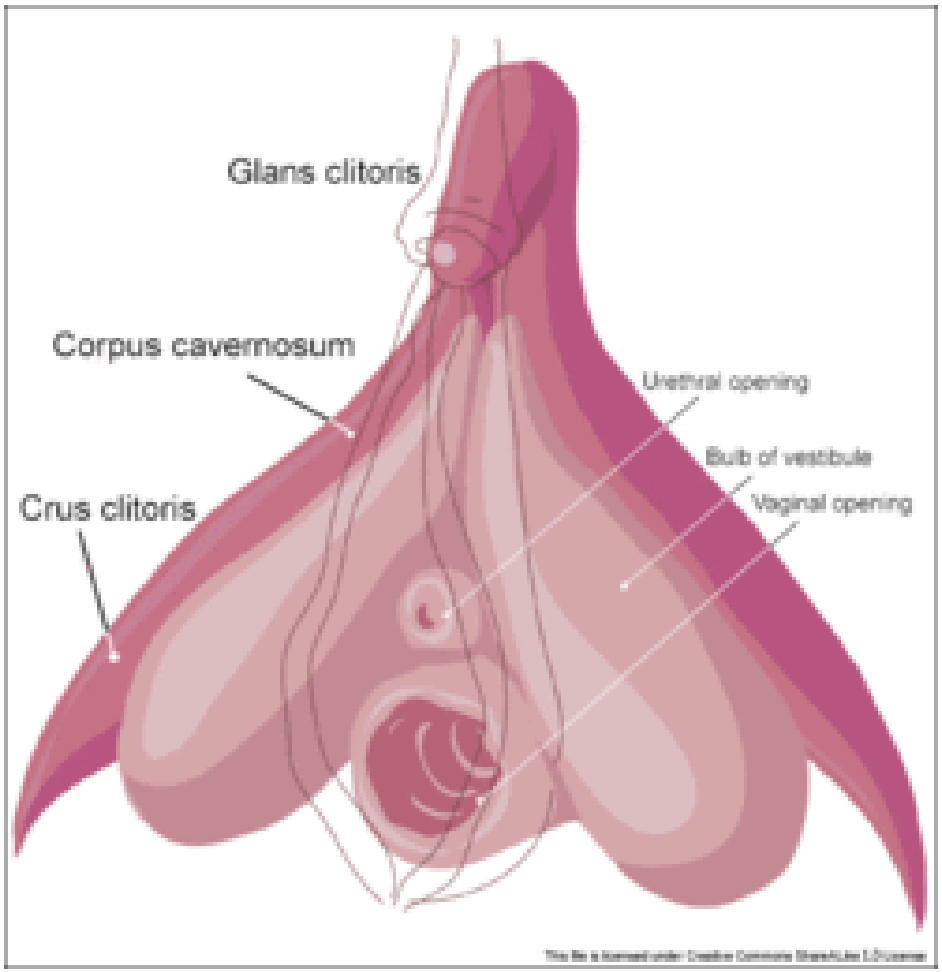
Clinical Support

- Sheep study demonstrated collagen remodeling
  - No evidence of necrosis or scarring
  - Clear evidence of collagen reformation

- First in Women Non-Significant Risk IRB study demonstrated safety and efficacy

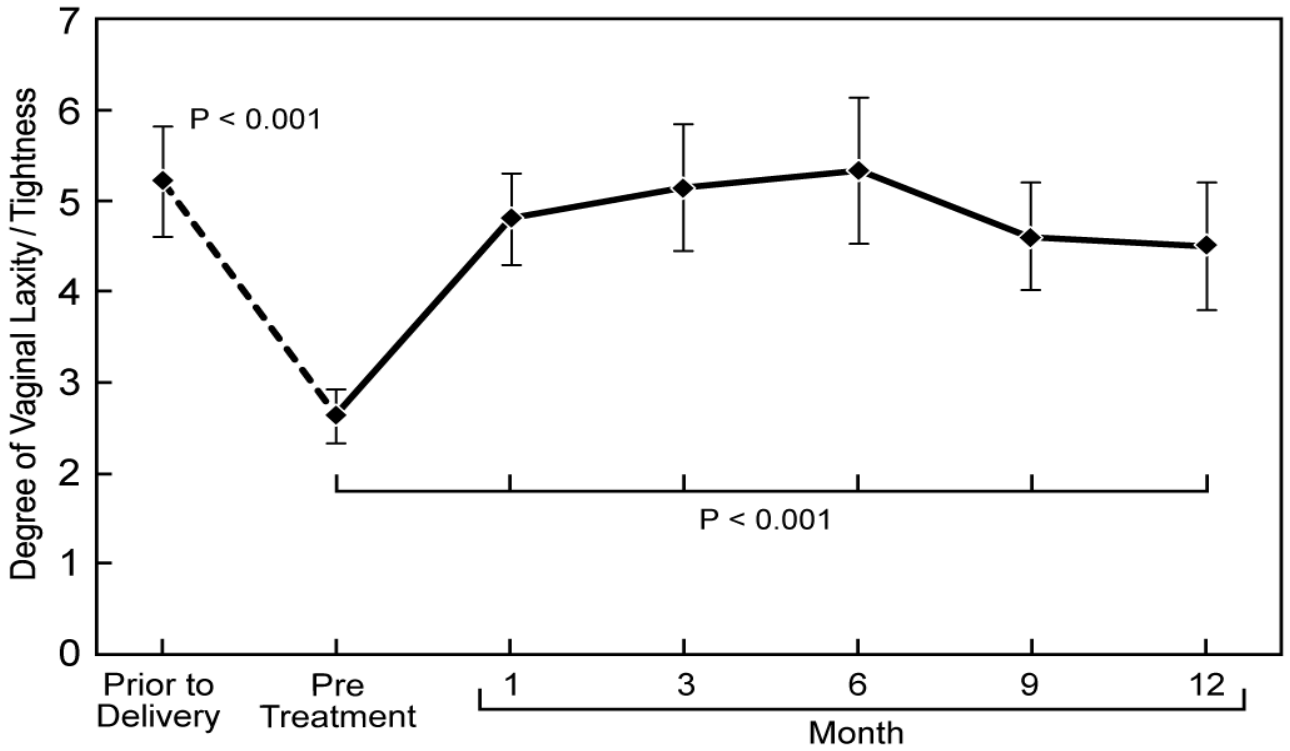
- Widely accepted research
  - Six poster presentations (ACOG, AUGS, ISSWSH, ISSM)
  - Three podium presentations (AAGL, ICS/IUGA, SPIE)
  - Journal of Sexual Medicine article (Sept 2010)
  - Journal of Women's Health (Nov 2013)

Mechanism of Action



First In Woman Study

Subject Self Report – Vaginal Laxity/Tightness Questionnaire (VLQ)



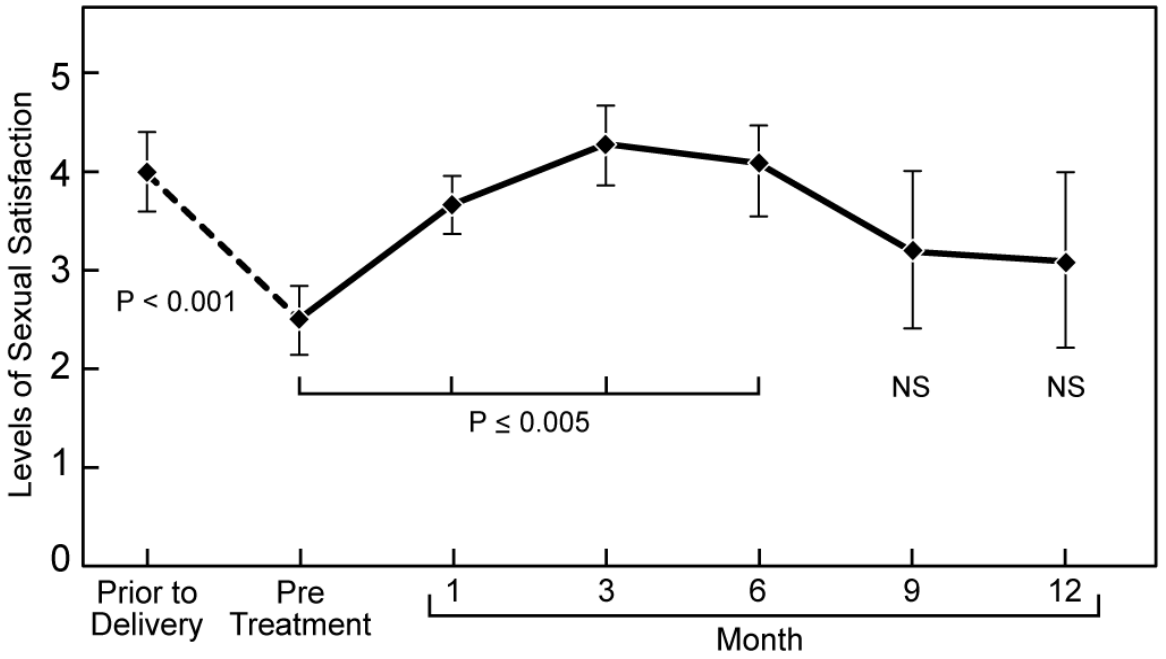
Vaginal Laxity Questionnaire (VLQ), subject's response category (corresponding numerical code): Very Tight (7), Moderately Tight (6), Slightly Tight (5), Neither Tight nor Loose (4), Slightly Loose (3), Moderately Loose (2), Very Loose (1)

Values are means ± 95% confidence interval (error bars) at each assessment. P values compare. Scores at each assessment relative to score at Pre-treatment (Wilcoxon signed rank test).

First In Woman Study (cont' d)

Subject Self Report– Sexual Satisfaction Questionnaire (SSQ)

Cohort A – 12 patients who reported decrease in sexual satisfaction post birth



Sexual satisfaction: Excellent [5], very good [4], good [3], fair [2], poor [1], none [0]

Present

Present

- Currently available in Hong Kong, Japan, and Canada
- CE mark allows Viveve System sales in Europe; launching into select European countries in early 2015
- Working with FDA to finalize IDE study protocol for U.S.
- To date, over 400 procedures performed without SAEs

Future

VIVEVE I Study

VIveve Treatment of the **V**aginal Introitus to **EV**aluate **E**fficacy

Post-Market, Parallel Group Study Design

Design:

- A prospective, longitudinal, randomized, single-blind, sham controlled clinical study
- Designed to demonstrate that active treatment (i.e., Viveve Procedure) is superior to the sham treatment for the primary effectiveness and safety endpoints.
- The active treatment group will receive a treatment dose of 90 J/cm^2 and the sham group will receive a sub-therapeutic dose of 1 J/cm^2.
- Subjects will be seen at one, three, and six months post treatment

VIVEVE I Study

Number of Evaluable Subjects to be Enrolled

- 113 subjects in 2:1 randomization scheme (75 subjects in the active arm and 38 subjects in the sham arm)

Clinical Sites

- Up to ten (10) clinical sites

Study Population

- Pre-menopausal females 18 years of age or older who have experienced at least one full term vaginal delivery (>36 completed weeks gestation) at least 12 months prior to enrollment date.

VIVEVE I Study

Primary Effectiveness Endpoint

- The proportion of subjects in the active arm as compared to the proportion of the subjects in the sham arm reporting no vaginal laxity at six months post-intervention
- "No vaginal laxity" is operationally defined as a score > 4 on the VSQ, a patient reported global assessment of vaginal laxity

Primary Safety Endpoint

- The proportion of subjects in the active arm experiencing an AE by six months post-treatment as compared to the proportion of the subjects in the sham arm experiencing an AE by six months post- intervention.

VIVEVE I Study

Secondary Effectiveness Endpoints

- The percent change in Vaginal Introitus Laxity Inventory (VALI) mean score from baseline to six months post- intervention in the active arm compared to the percent change in the Vaginal Introitus Laxity Inventory (VALI) mean score from baseline to six months post-intervention in the sham arm.
- The percent change in Total FSFI mean score from baseline to six months post- intervention in the active arm in contrast to the percent change in Total FSFI mean score from baseline to six months post-intervention in the sham arm.
- The percent change in Female Sexual Distress Scale-Revised (FSDS-R) mean score from baseline to six months post- intervention in the active arm in contrast to the percent change in FSDS-R mean score from baseline to six months post- intervention in the sham arm.

Thank you for your kind attention

Questions and Answers